



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

PETER T. O'HEERON and
PATRICK C. NEWLIN

Serial No.: 09/994,321

Filed: November 26, 2001

For: TROCAR

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Group Art Unit: 3731

Examiner: THALER, MICHAEL H.

CERTIFICATE OF EXPRESS MAILING

37 C.F.R. §110

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BRIEF ON APPEAL

Assistant Commissioner for Patents
Alexandria, VA. 22313

ATTN: BOX APPEAL BRIEF-PATENTS

Sir:

Pursuant to 37 C.F.R. § 1.192, Assignee NeoSurg Technologies, Inc. files this brief in triplicate in support of its appeal from the final rejection mailed January 26, 2004 in the above-identified patent application. A request for a one month extension of time to file this brief is being filed concurrently with this brief. Since the Assignee is a small entity, a check in the amount of \$220.00 is enclosed as the requisite fee (\$165 for filing of the brief plus \$55 for extension fee). If this check is inadvertently not enclosed or is insufficient in any respect, the Patent and Trademark

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I. REAL PARTY IN INTEREST

The real party in interest in this application and appeal is NeoSurg Technologies, Inc., 17300 El Camino Real, Suite 100, Houston, Texas 77058, the Assignee of the above-identified application.

II. RELATED APPEALS AND INTERFERENCES

Neither the Assignee nor the Assignee's legal representatives know of any other appeal or interference which will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 6-10 are the claims on appeal and are set forth fully in Appendix A to this brief. A final rejection of claims 6-10 was mailed on January 26, 2004.

IV. STATUS OF AMENDMENTS

No amendment was filed subsequent to the final rejection of January 26, 2004.

V. SUMMARY OF THE INVENTION

The present invention relates to a surgical instrument known as a trocar which is used in endoscopic surgery to pierce or puncture an anatomical cavity to provide communication with the cavity during a surgical procedure. In particular, the present invention relates to a tip configuration for the obturator of the trocar. (*see* Specification, p. 1)

It is well-known that endoscopic surgery constitutes a significant method today of performing surgeries and is the surgical procedure of choice because of the patient care advantages over “open surgery.” One form of endoscopic surgery is a laparoscopic surgery, which usually has a post-operative recovery time which is substantially less than the recovery time associated with open surgeries. *Id.* Additionally, laparoscopic surgery achieves decreased incidents of post-operative abdominal adhesions, decreased post-operative pain and enhanced cosmetic results. *Id.*

A trocar may be used in a laparoscopic surgical procedure to penetrate the abdominal wall once the abdominal cavity has been insufflated with carbon dioxide. A trocar includes a body assembly, a cannula assembly which is attached to the body assembly to form a bore through the body assembly, and a pointed element called an obturator. The obturator slides in the bore of the trocar and has a piercing tip at its end. After insertion of the trocar through the abdominal wall of the patient, the obturator is removed by the surgeon while leaving the cannula protruding through the body wall. Laparoscopic instruments can then be inserted through the cannula to view internal organs and to perform surgical procedures. *Id.*

In accordance with the present invention, a trocar is provided which comprises a housing assembly 10 and a cannula assembly 20 which is attached to the housing assembly 10 (Specification, p.3; FIG 1). An axial bore exists through the housing and cannula, i.e. from the proximal end of the housing to the distal end of the cannula. (Specification, p.3). A trocar in accordance with the present invention also includes an obturator assembly 30 for sliding engagement in the axial bore. The obturator assembly comprises a shaft 31 having a longitudinal axis and having a distal piercing end 33 for insertion into the body of a patient. *Id.* (Specification, p.3; FIG 1). A piercing tip 35 is

removably connected to the distal piercing end of the obturator shaft. *Id.* The piercing tip 35 is illustrated in FIG 2 which is reproduced below:

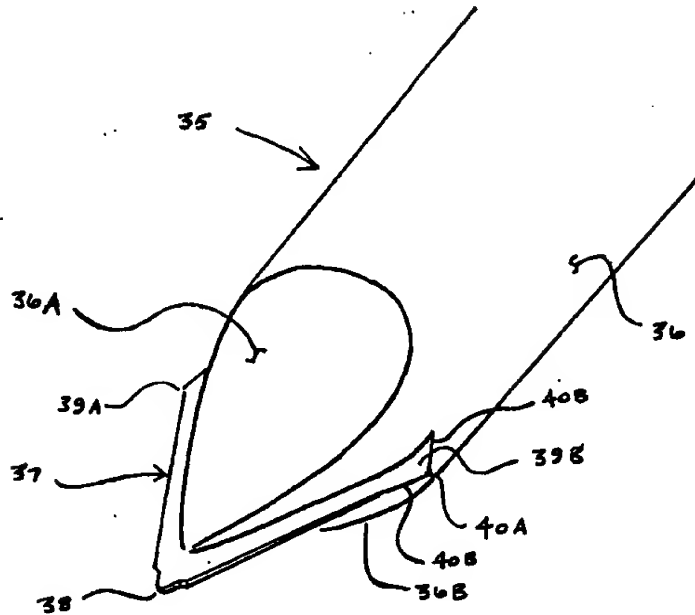


FIG. 2

The piercing tip 35 comprises a body 36 having upper and lower faces 36A and 36B, respectively, which taper away from the shaft 31 and an insert blade 37 residing partly within the body of the piercing tip and protruding outward away from the body of the piercing tip. The insert blade 37 comprises a non-conical, blunt head 38 and two wing elements 39A and 39B having lateral edges located 180 degrees apart between the upper and lower faces of the body.

By using the foregoing design for the tip of the obturator, applicants believe that less force will be required to insert the obturator into a patient than the force required with conventional

trocars. Additionally, the penetration forces act away from the tip of the obturator, which eases the penetration of the trocar. Further, the blunt head of the piercing tip - - as opposed to a sharp, conical head - - prevents internal structures from being cut if encountered during insertion of the obturator assembly. (Specification, p.3).

VI. ISSUE ON APPEAL

1. Did the Examiner err in rejecting claims 6-10 under 35 U.S.C. § 103 as being unpatentable over the combination of U.S. Patent No. 5,441,041 to Sauer ("Sauer patent") and U.S. Patent No. 5,817,061 to Goodwin ("Goodwin patent"), each in view of the other?

VII. GROUPING OF CLAIMS

The patentability of claims 6-10 stand or fall on the patentability of claim 6.

VIII. ARGUMENT

A. Standards With Respect to Establishing a *Prima Facie* Case of Obviousness

Three criteria must be established in order to make out a *prima facie* case of obviousness based on a combination of prior art references. First, there must be some suggestion or motivation, either in the references used by the Examiner or in the knowledge generally available to one of ordinary skill in the art, to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference or references, when combined, must teach or suggest all of the claimed limitations. *See* M.P.E.P. § 2143; *see also In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).

The law is well-established that, before a conclusion of obviousness of a patent claim can be made based on a combination of references, there must have been a suggestion or motivation to lead

an inventor to combine those references. *ACS Hospital Systems, Inc. v. Monte- fiore Hospital*, 732 F.2d 1572, 1577 (Fed.Cir. 1984); *see also Vikase Corp. v. American National Cab Co.*, 261 F.3d 1316, 1327 (Fed.Cir. 2001) (judgment upholding validity of patents in suit affirmed in absence of suggestion, motivation or teaching to combine the prior art); *Jazz Photo Corp. v. U.S. Int'l Trade Comm'n*, 264 F.3d 1094, 1109 (Fed.Cir. 2001) (In the absence of a suggestion to combine prior art references, the patented process was not rendered obvious); *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1385 (Fed.Cir. 2001); *WMS. Gaming, Inc. v. Int'l Game Technology*, 184 F.3d 1339, 1359 (Fed.Cir. 1999); *In re Dance*, 160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637 (Fed.Cir.1998); *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed.Cir.1984). The teaching or suggestion to make the claimed combination must be found in the prior art, not in the applicant's disclosure. *Vaeck*, 947 F.2d. at 493.

Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference. *See B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582, 37 USPQ2d 1314, 1318 (Fed.Cir.1996).

If the proposed modification or combination of the prior art would change the principle of the operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). In *Ratti*, the claims were directed to an oil seal comprising a bore engaging portion with outwardly biased resilient spring fingers inserted in a resilient sealing member. The primary reference relied upon in a rejection based on a combination of references disclosed an oil seal wherein the bore engaging portion was reinforced by a cylindrical sheet metal casing. The reference disclosed that the device required rigidity for operation, whereas the claimed invention required

resiliency. The court reversed the rejection holding the “suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate.” 270 F.2d at 813, 123 USPQ at 352.

A critical step in analyzing the patentability of claims pursuant to section 103 is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. *In re Dembiczak*, 175 F.3d 994, 999 (Fed.Cir.1999). Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher." *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed.Cir.1983).

B. The Examiner’s § 103 Rejections of Claim 6 are Erroneous

1. The Final Rejection

In the Office Action mailed January 26, 2004 (hereafter “Office Action”), the Examiner made a § 103 rejection of claims 6-10 based on the combination of the Sauer patent and the Goodwin patent, each in view of the other.

2. The § 103 Rejection of Claim 6 Based on Sauer in View of Goodwin was Erroneous

In making the final rejection of claim 6 under § 103 based on Sauer in view of Goodwin, the Examiner stated that “[it] would have been obvious to make the blade edge of Sauer

[sic] al blunt ... (Office Action, p.3). Significantly, there is no suggestion in Goodwin to substitute a blunt blade for the sharp blade in Sauer.

Enroute to his erroneous conclusion of obviousness, the Examiner misapprehends the disclosure of Sauer. The Examiner blithely asserts that Sauer is “silent” on whether the blade 34 is blunt or sharp (Office Action, p.2). The Sauer patent, however, repeatedly describes the blade 34 in the disclosed optical trocar as being a “cutting blade” or as having a “cutting tip.” That description occurs twelve times in the following sections of the Sauer patent: (a) the Background of the Invention Section at col. 1, lines 56-58; (b) the Brief Description of the Drawings Section at col. 2, lines 57 and 63 and col. 3, line 9; (c) the Detailed Description Section at col. 3, lines 53-55, lines 58-60 and line 61 and at col. 5, lines 21-24; and (d) the claims in claims 1, 5 and 9. Accordingly, contrary to the Examiner’s conclusion, the blade 34 in Sauer is sharp. That being the case, what motivation exists to take the sharp blade of Sauer that is supposed to cut tissue and to make it blunt so that it will not cut tissue? The answer is simple — none.

The sharp blade in Sauer is deployed when tissue is to be cut . Replacing the sharp blade with a blunt blade results in a trocar in which tissue is not cut when the blade is deployed. Therefore, to modify Sauer to make the sharp blade of Sauer a blunt blade as the Examiner asserts would change the principle of operation of Sauer. The teachings of Sauer and Goodwin are not, therefore, properly combinable to make the section 103 rejection of claim 6 made by the Examiner. *Ratti*, 270 F.2d at 813. Accordingly, the § 103 rejection must be reversed.

3. The § 103 Rejection of Claim 6 Based on Goodwin in View of Sauer Was Erroneous

Alternatively, the Examiner asserts that claims 6-10 would have been obvious based

on the Examiner's combination of the Goodwin patent in view of the Sauer patent. The Examiner asserts that "[i]t would have been obvious to extend blades 18 of Goodwin et al. to the tip of the obturator....(Office Action, p.3). Once again, however, no suggestion or teaching exists in the references to support the Examiner's conclusion.

The Examiner's reasoning in reaching his erroneous conclusion of obviousness is as follows.

First, the Examiner asserts that the Goodwin patent "discloses blunt edged blades 18 but fails to disclose that they meet to form a single 'blade'." The Examiner then continues by stating that "Sauer et al. teaches that blade edges (at 34) on a conical obturator should extend to the tip (or head) of the obturator and meet and thus form a blade apparently in order to dissect tissue effectively" (Office Action, p.3). To support his latter quoted statement, the Examiner cites two portions of the Sauer patent namely:

(a) Column 5, lines 19-24 which reads:

Pressure is applied to hand grip 21 in the distal direction to penetrate the body tissue. The movement of blade 34 facilitates cutting of the body tissue, thus permitting the surgeon to apply minimal pressure to hand grip 21 to penetrate the body tissue.

and (b) Column 3, lines 53-63 which reads:

Referring again to FIG. 2, the cutting portion 32 of obturator assembly 12 includes a cutting blade 34 connected to actuating assembly 36. Actuating assembly 36 is provided to move blade 34 between a non-deployed position (FIG. 1A) and a deployed position (FIG. 5A) which will be described in more detail below. The cutting blade 34 is preferably centered with respect to the outer surface of the image directing member as shown. Thus, in visualization, the cutting blade is seen as a thin line through the center, i.e. bisecting, the viewing field so as not to obstruct viewing of the body.

The quoted portions of the Sauer patent do not stand for the proposition for which they are cited by the Examiner and, in any event do not constitute any teaching or suggestions that the blunt blade edges in Goodwin should be extended to meet at the tip. Rather, the first quoted portion of the Sauer patent describes movement of the entire cutting blade, as a whole, for the purpose of cutting body tissue. The second quoted portion of the Sauer patent merely describes how the cutting blade is deployed and the positioning of the blade vis-à-vis the image directing number.

Significantly, Goodwin teaches that the tip 15 of his disclosed obturator preferably has a “conical configuration to facilitate the penetration or dissection of tissue.” (Goodwin, col. 4, lines 31-32). According to the Examiner on page 2 of the Office Action, insert blade 34 of Sauer has a non-conical head at the tip. Therefore, what motivation exists to take an obturator that has a conical tip and modify it to have a non-conical tip. Again, the answer is simple — none.

**4. The § 103 Rejections Are Based on Impermissible
Hindsight Reconstruction**

Notably, the Examiner takes inconsistent positions about what is disclosed by Sauer. When Sauer is used as the primary reference by the Examiner, the Examiner asserts that insert blade 34 of Sauer comprises a non-conical tip (Office Action, p.2). However, when Sauer is used as the secondary reference by the Examiner, the Examiner states that “Sauer et al. teaches that blade edges (at 34) on a conical obturator should extend to the tip (or head) of the obturator...” (Office Action, p.3).

It is abundantly clear from the Examiner's use of Sauer as a "nose of wax" and from the remainder of the Office Action that the Examiner has attempted, without any suggestion to combine Sauer and Goodwin, to piece applicants' invention together from Sauer and Goodwin using applicants' invention as a template. Such a procedure is the essence of hindsight reconstruction [*Dembiczak*, 175 F.3d at 999] and is improper as a matter of law. *Texas Instruments Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165 (Fed.Cir.1993).


X. CONCLUSION

The Examiner's final rejection of claims 6-10 of this application under 35 U.S.C. § 103 is erroneous. The Examiner has not made out a *prima facie* case of obviousness because there is not any suggestion, motivation or teaching to combine the references as the Examiner has combined them, and the Examiner's combination changes the principle of operation of the prior art being modified. The § 103 rejection is also erroneous because it is based on hindsight reconstruction.

The Examiner's final rejection must, therefore, be reversed, and such action is respectfully requested.

Respectfully submitted,

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APPENDIX "A"

6. A trocar, comprising:

- (a.) a housing assembly;
- (b.) a cannula assembly attached to the housing assembly and defining an axial bore therethrough; and
- (c.) an obturator assembly for sliding engagement through the axial bore defined by the cannula assembly, said obturator assembly comprising a shaft having a piercing end for insertion into a patient and a piercing tip removably connected to the piercing end of the shaft, said piercing tip comprising:
 - (i.) a body having an upper face and a lower face tapering away from the shaft; and
 - (ii.) an insert blade residing partially within the body of the piercing tip and protruding outward away from the body of the piercing tip, said insert blade comprising a non-conical, blunt head and two wing elements having lateral edges located 180 degrees apart between the upper face and lower face of the body.

7. The trocar of claim 6, wherein the insert blade is fabricated from metal.
8. The trocar of claim 6, wherein the insert blade is fabricated from plastic.
9. The trocar of claim 6, wherein said shaft further comprises a handling end for gripping.
10. The trocar of claim 9, further comprising an arcuate-shaped cap attached to the handling end of the shaft.